



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): LEVY, Andrew                      Examiner: GOLDBERG, JEANINE ANNE

Serial No.: 10/748,177                      Group Art Unit: 1634

Filed: December 31, 2003

Title: METHOD OF PREDICTING A BENEFIT OF ANTIOXIDANT THERAPY FOR  
PREVENTION OF CARDIOVASCULAR DISEASE IN HYPERGLYCEMIC  
PATIENTS

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☒ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or

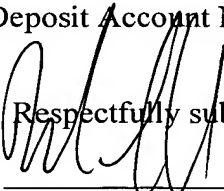
II) ☒ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☒ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.

- III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,
1. The undersigned hereby states:
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- b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and
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**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

  
Respectfully submitted,

\_\_\_\_\_  
Mark S. Cohen  
Attorney/Agent for Applicant(s)  
Registration No. 42,425

Dated: March 14, 2006

**Pearl Cohen Zedek Latzer, LLP**  
1500 Broadway, 12th Floor  
New York, NY 10036  
Phone: (646) 878-0804  
Fax: (646) 878-0801

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**Complete if Known**

<b>Application Number</b>	<b>10/748,177</b>
<b>Filing Date</b>	<b>December 31, 2003</b>
<b>First Named Inventor</b>	<b>LEVY, Andrew</b>
<b>Group Art Unit</b>	<b>1634</b>
<b>Examiner Name</b>	<b>GOLDBERG, JEANINE ANNE</b>
<b>Attorney Docket Number</b>	<b>P-7339-US</b>

**(use as many sheets as necessary)**

Sheet	1	of	7	Attorney Docket Number	P-7339-US
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Date  
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet	2	of	7	Attorney Docket Number	P-7339-US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	B	Bublin, et al, Eur Heart J. 2003; 24:2099-2107	<input type="checkbox"/>
	C	De Bacquer, et al, Athrosclerosis 2001; 157:161-1666	<input type="checkbox"/>
	D	Hong, et al, Hum Hered 1997; 47:283-7	<input type="checkbox"/>
	E	HOPE Study Investigators NE J. Med 2000;342:154-160	<input type="checkbox"/>
	F	Lind, et al, Angiology 2003; 54:401-410	<input type="checkbox"/>
	G	Nishikawa, et al, Nature 2000; 404:787-790	<input type="checkbox"/>
	H	Ohgami, et al, J Diabetes Complic 2002; 16:56-59	<input type="checkbox"/>
	I	Stamler, et al, Diabetes Care 1993; 16: 434-444	<input type="checkbox"/>
	J	Steinberg D, (1997) "Low density lipoprotein oxidation and its pathobiological significance." J Biol Chem; 272-20963-6	<input type="checkbox"/>
	K	Williams, et al, (1992) "Dietary vitamin E and the attenuation of early lesion development in modified Watanabe rabbits. Atherosclerosis." Atherosclerosis; 94:153-159	<input type="checkbox"/>
	L	Brown, et al, "Simvastatin and niacin, antioxidant vitamins, or the combination for the prevention of coronary disease." NE J Med 2001; 345: 1538-92	<input type="checkbox"/>

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		Attorney Docket Number	P-7339-US

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	M	GISSI, Lancet 1999; 354:4477-55	<input type="checkbox"/>
	N	Hodis, et al, Circulation 2002; 106:1453-59	<input type="checkbox"/>
	O	Jiang, et al, J Biol Chem 202; 277:31850-6	<input type="checkbox"/>
	P	Levy, et al, J Am Coll Card 2002; 40: 1984-90	<input type="checkbox"/>
	Q	Marchioli, et al, Lipids; 2001: 36 Suppl: S53-63	<input type="checkbox"/>
	R	Melamed-Frank, et al, Blood 2001; 98: 3693-98	<input type="checkbox"/>
	S	Steinberg, et al, Circulation 2002; 105: 2107-2111	<input type="checkbox"/>
	T	UK Prospective Study Group Diab Care 1998; 21: 1271-1277	<input type="checkbox"/>
	U	Waters, et al, JAMA 2002; 288: 2342-40	<input type="checkbox"/>
	V	Witztum, et al, Trends Cardio Med 2001; 11:93-102	<input type="checkbox"/>
	W	Barany, PCR Methods and Applic., 1:5 (1991)	<input type="checkbox"/>

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	X	Barany, Proc. Natl Acad. Sci., 88: 189 (1991)	<input type="checkbox"/>
	Y	Brown, et al, N Eng J Med 2001; 345: 1583-1592	<input type="checkbox"/>
	Z	Fahy, et al, "Self-sustained sequence replication (3SR): an isothermal transcription-based amplification system alternative to PCR." PCR Meth. Appl., 1:25-33 (1991)	<input type="checkbox"/>
	AA	Guatelli, et al, Proc. Natl Acad. Sci., 87:1874-1878 (1990)	<input type="checkbox"/>
	BB	Mullis, PCR Methods Applic. 1:1 (1991)	<input type="checkbox"/>
	CC	The Heart Outcomes Prevention Evaluation Study Investigators N Eng J Med 2000; 342: 154-160	<input type="checkbox"/>
	DD	Wu and Wallacc, Genomics 4: 560 (1989)	<input type="checkbox"/>
	EE	Barlow and Lehrach, Trends Genet., 3:167 (1987)	<input type="checkbox"/>
	FF	Conner, et al, Proc. Natl Acad. Sci. 80: 278-282 (1983)	<input type="checkbox"/>
	GG	Farr, et al, Proc. Natl. Acad. Sci. 85: 1629-1633-(1988)	<input type="checkbox"/>
	HH	Gogos, et al, "Detection of single base mismatches of thymine and cytosine residues by potassium permanganate and hydroxylamine in the presence of tetralkylammonium salts." Nucl. Acids Res., 18: 6807-6817 (1990)	<input type="checkbox"/>

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	II	Kwok, et al, Nucl. Acids Res., 18:999 (1990)	<input type="checkbox"/>
	JJ	Lyons, et al, Science 249: 655-659 (1990)	<input type="checkbox"/>
	KK	Perlman and Butow, Science 246: 1106 (1989)	<input type="checkbox"/>
	LL	Urdea, et al, Gene 61: 253-264 (1987)	<input type="checkbox"/>
	MM	Vogelstein, et al, N Eng. J. Med. 319: 525-532 (1988)	<input type="checkbox"/>
	NN	Abrams, et al, Genomics 7: 463-475 (1990)	<input type="checkbox"/>
	OO	Borrensens, et al, Proc. Natl Acad. Sci. USA 88: 8405 (1991)	<input type="checkbox"/>
	PP	Hayashi, Sekya and colleagues PCR Meth. Appl. 1: 34-38 (1991)	<input type="checkbox"/>
	QQ	Lerman and Silverstein, Meth Enzymol, 155: 482-501 (1987)	<input type="checkbox"/>
	RR	Liu and Sommer, PCR Methods Applic 4: 97 (1994)	<input type="checkbox"/>
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	TT	Scholtz, et al, Hum. Mol. Genet. 2: 2155 (1993)	<input type="checkbox"/>
	UU	Sheffield, et al, Proc Natl. Acad. Sci. 86: 232-236 (1989)	<input type="checkbox"/>
	VV	Smith, et al, Genomics 3:217-223 (1988)	<input type="checkbox"/>
	WW	Wartell, et al, Nucl. Acids Res., 18: 2699-2701 (1990)	<input type="checkbox"/>
	XX	Campo, et al, Cardiovasc Drug Rev 1997; 15: 157-173	<input type="checkbox"/>
	YY	Kita, et al, PNAS USA 1987; 84: 7725	<input type="checkbox"/>
	ZZ	Mak, et al, Pharma Res. 2002; 45: 27-33	<input type="checkbox"/>
	a	Meng, et al, Bioorg Med Chem Ltrs 2002; 12: 2545-48	<input type="checkbox"/>
	b	Sagach, et al, Pharma Res 202; 45: 435-439	<input type="checkbox"/>
	c	Yoshida, et al, Altheroscler 2002; 162: 111-117	<input type="checkbox"/>
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